510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92.

Submitted By: Poriferous, LLC
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Contact Person: Aaron Noble, President/CEO
Poriferous, LLC, Inc

Date Prepared: January 10th 2014

Device Name and Classification:

Trade/Proprietary Name:	Su-Por® Surgical Implants
Common Name:	Porous HD Polyethylene (HDPE) Implants
Classification Name:	Ear, Nose, and throat synthetic polymer material.
Class:	II
Regulation:	21 CFR 878.3500,
Product Code:	KKY
Subsequent Product Code	FWP

Legally Marketed Predicate Devices:

POREX Surgical INC. (now owned by Stryker® Craniomaxillofacial) MEDPOR® *Surgical Implant Material:* Preformed Cranial and Facial Implants – 510(k) # K922489

Matrix Surgical USA OmniPor® Surgical Implants – 510(k) #K123908

Device Description:

The Su-Por® Surgical Implants are marketed as single use sterile implants with various shapes and sizes for different areas of the craniofacial skeleton. The applications include non-load bearing augmentation and/or reconstruction of the craniofacial skeleton.
The raw material used for the Su-Por® Surgical Implants is high-density polyethylene when molded into the implants becomes a porous high-density polyethylene. Polyethylene has a long history of use in surgical implantable products. The interconnecting open pore structure of the Su-Por® Surgical Implants allow for tissue in growth. The material used to manufacture the Su-Por® Surgical Implants has been utilized in reconstruction and soft tissue repair for many years. There is a long history of the use of porous polyethylene implants for enucleation and evisceration, as well as for many applications in craniofacial reconstruction and augmentation, with a history of safety and performance. The implants are single use and provided sterile by ethylene oxide (EO) terminal sterilization.

Indications for Use:

Su-Por® Surgical Implants in block, sheet, and anatomical shapes are intended for non-weight bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma. Su-Por® Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillofacial skeleton.

Similarities and Differences to the Predicate Devices:

The same raw materials, manufacturing processes, packaging materials, performance standards, and the same indications for use are used in the Su-Por and the predicate devices.

The following table provides a comparison of the proposed device, and the predicate devices;

Device Name	**Proposed Device** Su-Por® Surgical Implants; Preformed block, sheet, and anatomical shapes.	**Predicate #1** MEDPOR® Surgical Implant Material; Preformed Cranial & Facial Implants	**Predicate #2** OmniPor® Surgical Implants; Preformed block, sheet, and anatomical shapes.
510(k) Number	This Submission	K922489	K123908
Intended Use	Su-Por® Surgical Implants in block, sheet, and anatomical shapes are intended for non-	For augmentation or restoration bony contour in craniofacial	OmniPore® Surgical Implants in block, sheet, and anatomical shapes are intended for

	weight bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma. Su-Por® Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillofacial skeleton.	defects.	nonweight bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma. OmniPore Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillofacial skeleton.
Material	A linear, high-density polyethylene biomaterial	A linear, high-density polyethylene biomaterial	A linear, high-density polyethylene biomaterial
Design	Preformed shapes including sheets, blocks, spheres, and anatomical shapes.	Preformed shapes including sheets, blocks, spheres, and anatomical shapes.	Various shapes and sizes for differing areas of the craniofacial skeleton.
Sterile / Non-Sterile	Sterile	Sterile	Sterile
Sterilization Method	EtO	EtO	EtO
Packaging	Double Tyvek Pouch	Double Tyvek Pouch	Double Tyvek Pouch
Biocompatible	Yes	Yes	Yes
Reusable	No	No	No

Summary of Testing:

The Su-Por Surgical Implants were tested to the biocompatibility standards to demonstrate that they are substantially equivalent materials as the predicate devices in regards to Cytotoxicity, ISO Systemic Toxicity, ISO Intracutaneous Study, USP Pyrogen Study, and ISO Muscle Implantation Study. The Su-Por Surgical Implants completed sterilization validation to validate that they are sterile devices for implantation as equivalent to the predicate devices. The Su-Por Surgical Implants completed mechanical testing specific to impact testing, flexural testing, tensile strength testing, purity testing per USP, and porosity testing.

The testing listed above assures the device is safe and effective for its intended use.

Substantial Equivalence Conclusions:

The Su-Por® Surgical Implants have the same intended use and indications for use, and the same technological characteristics and principles of operation as

the predicate devices. It is concluded that the proposed device is substantially equivalent, based on the nonclinical testing (discussed above) that demonstrates that the device is as safe, as effective, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Poriferous, LLC
Mr. Aaron Noble
President/Chief Executive Officer
535 Pine Road, Suite 206
Newnan, Georgia 30263

June 13, 2014

Re: K140437
Trade/Device Name: Su-Por Surgical Implant
Regulation Number: 21 CFR 878.3500
Regulation Name: Polytetrafluoroethylene with carbon fibers composite implant material
Regulatory Class: Class II
Product Code: KKY, FWP
Dated: May 12, 2014
Received: May 16, 2014

Dear Mr. Noble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Neil R Ogden -S
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For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Applicant: Poriferous, LLC.

510(k) Number (if known): K140437

Device Name: Su-Por Surgical Implant

Indications for Use:

Su-Por Surgical Implants in block, sheet, and anatomical shapes are intended for non-weight bearing applications of craniofacial reconstruction/ cosmetic surgery and repair of craniofacial trauma. Su-Por Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillofacial skeleton.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter L. Hudson -S